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EXAMINER	
SASAN, ARADHANA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,335	STANIFORTH ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-12 and 39-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-12 and 39-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks, amendments, and Request for Continued Examination filed on 09/14/09 are acknowledged.

2. Claims 3, 6, and 13-38 were cancelled. New claim 53 was added.

3. Claims 1-2, 4-5, 7-12, and 39-53 are included in the prosecution.

Continued Examination under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/09 has been entered.

NEW REJECTIONS:

The following is a list of new rejections:

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 53 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Claim 53 recites the limitation of "wherein said excipient is not obtained by wet granulation."

After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. The specification discloses an excipient **useful** in direct compression methods and wet granulation methods (Page 8, lines 13-18). The only dry blending of microcrystalline cellulose and silicon dioxide relates to a control formulation (Page 37, lines 18-18, Example 4). There is no disclosure of the excipient "not obtained by wet granulation."

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the limitation of "wherein said excipient is not obtained by wet granulation." It is unclear how a granulation process involving an **aqueous** slurry and microcrystalline cellulose in the form of a **wet** cake can **not** be a wet granulation process. Clarification is required.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-2, 7-12, 39-40 and 45-50 **remain** rejected and **new claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Botzolakis et al. (US 4,910,023).

The claimed invention is a method for preparing a tablet, consisting essentially of the steps of: forming an aqueous slurry containing a mixture of microcrystalline cellulose in the form of a wet cake and silicon dioxide having a particle size from about 1 nm to about 100μm; drying the slurry to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with the silicon dioxide. The amount of silicon dioxide is from about 0.1% to about 20% relative to the amount of microcrystalline cellulose, by weight. Then, a moisture-sensitive active ingredient is mixed with the excipient in a ratio from about 1:99 to about 99:1 to obtain a mixture. The mixture is compressed into a tablet.

Botzolakis teaches that "various unpleasant flavored drugs can be processed by a unique wet granulation process wherein a slurry of the drug in water is dried in combination with colloidal silicon dioxide and, in a particularly preferred embodiment

microcrystalline cellulose is used with the colloidal silicon dioxide adsorbing on the drug particles" (Col. 2, lines 11-17). Unpleasant flavored drugs are defined as "drugs which are unpleasant tasting and/or smelling and/or are hygroscopic and/or tacky" (Col. 2, lines 18-21). Examples of hygroscopic or moisture sensitive drugs include "oxtriphylline, procainamide HCl, gemfibrozil, disopyramide phosphate, fenoprofen calcium, atenolol, piracetam, rifamprin, clindamycin HCl, cefaclor, cefadroxil, cephrabine, ascorbic acid, acetysalicylic acid, methocarbamol, methyldopa, ranitine HCl, ethionamide, divalproex sodium, meprobamate, captopril, and aminophylline" (Col. 1, lines 14-25). The drug is present at a level of 30 to 70% by weight (Col. 2, lines 43-44). Example 1 comprises the hygroscopic active phenoxypyridine monosulfate, colloidal silicon dioxide and microcrystalline cellulose (Col. 3, lines 20-55). The drug is milled with colloidal silicon dioxide. An aqueous mixture of sodium lauryl sulfate and water is mixed with the combination of silicon dioxide and the drug. Crospovidone is then added to aid in disintegration. Colloidal silicon dioxide is then added and mixed for about 5 minutes followed by the addition of microcrystalline cellulose. The granulation is then dried in an oven at 50°C to a moisture content of less than 0.5% and further processed by milling through a 1B screen and then combined with calcium stearate, crospovidone and talc. Tablets are formed by compressing 1140 mg of the mixture to a hardness generally between 18 and 20 Kgm.

Botzolakis does not expressly teach drying a slurry of microcrystalline cellulose and silicon dioxide before mixing with a moisture-sensitive active ingredient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of making a tablet comprising drying a slurry containing a moisture sensitive active ingredient, colloidal silicon dioxide and microcrystalline cellulose, as suggested by Botzolakis, vary the addition of a moisture sensitive active ingredient to the slurry containing colloidal silicon dioxide and microcrystalline during the process of routine optimization, and produce the instant invention.

One of ordinary skill in the art would do this because during the process of routine experimentation the step of drying the microcrystalline cellulose and colloidal silicon dioxide in the drug slurry can be varied to adding the drug to the dried microcrystalline cellulose and colloidal silicon dioxide slurry. One with ordinary skill in the art would change the addition of drug to the dried microcrystalline cellulose and silicon dioxide mixture in order to optimize the taste masking and desired release profile of the drug. Botzolakis teaches that "a protective coating of silicon dioxide ... masks unpleasant taste and odor and also reduces the adhesive of the granulation onto the punch faces used in the manufacture of the granules. By adsorbing silicon dioxide on the particulate surface of the malflavored hygroscopic drug, the drug becomes not only easier to handle but the unpleasant tastes and/or odors are masked making the final product more susceptible to proper patient compliance" (Abstract).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 1 and 39, the limitation of a method for preparing a tablet would have been obvious over the method of preparing a tablet as taught by Botzolakis (Col. 3, lines 20-55). The limitation of forming an aqueous slurry containing a mixture of microcrystalline cellulose in the form of a wet cake and silicon dioxide would have been obvious over the aqueous mixture of sodium lauryl sulfate and water that is mixed with the combination of silicon dioxide and the drug, that is followed by the addition of microcrystalline cellulose (Col. 3, lines 20-55). One with ordinary skill in the art would change the addition of drug to the dried microcrystalline cellulose and silicon dioxide mixture in order to optimize the taste masking and desired release profile of the drug. Botzolakis teaches that "a protective coating of silicon dioxide ... masks unpleasant taste and odor and also reduces the adhesive of the granulation onto the punch faces used in the manufacture of the granules. By adsorbing silicon dioxide on the particulate surface of the malflavored hygroscopic drug, the drug becomes not only easier to handle but the unpleasant tastes and/or odors are masked making the final product more susceptible to proper patient compliance" (Abstract). The particle size of silicon dioxide is a manipulatable parameter that can be modified during the process of routine experimentation in order to achieve the desired dosage, release, stability and taste profile of the tablet. The limitation of the ratio of moisture sensitive active ingredient to the excipient (about 1:99 to about 99:1) would have been obvious over the drug that is present at a level of 30 to 70% by weight, as taught by Botzolakis (Col. 2,

lines 43-44). The limitation of compressing the mixture into a tablet would have been obvious over the compression taught by Botzolakis (Col. 3, lines 51-53).

Regarding instant claims 2 and 40, the limitations of colloidal silicon dioxide and wet granulation prior to compression would have been obvious over the colloidal silicon dioxide (Col. 3, Table 1, lines 25 and 29) and wet granulation prior to compression, as taught by Botzolakis (Col. 3, lines 39-52).

Regarding instant claims 7 and 45, the limitation of adding a further amount of the excipient to the wet granulated mixture would have been obvious over the wet granulation method taught by Botzolakis (Col. 3, lines 39-52). One with ordinary skill in the art would find it obvious to further add the microcrystalline cellulose and silicon dioxide in order to improve flowability and compressibility.

Regarding instant claims 8-12 and 46-50, the limitation of drying the slurry to so that the resultant excipient particles have a moisture content of from about 0.5 to about 15% would have been obvious over the drying that leads to a moisture content of less than 0.5%, as taught by Botzolakis (Col. 3, lines 46-47). One with ordinary skill in the art would find it obvious to modify the drying temperature during the process of routine experimentation in order to optimize the desired moisture content.

Regarding new claim 53, the limitation of "wherein said excipient is not obtained by wet granulation" is obvious over the method taught by Botzolakis since one of ordinary skill in the art would use various granulation methods during the process of routine experimentation. One of ordinary skill in the art would know that dry granulation

is indicated for granulating moisture sensitive or hygroscopic active ingredients since these actives need to be protected from exposure to water in order to prevent degradation.

Response to Arguments

11. Applicant's arguments, see Page 7, filed 09/14/09, with respect to the rejection of claims 1-2, 7-12, 39-40 and 45-50 under 35 U.S.C. 103(a) as being unpatentable over Botzolakis et al. (US 4,910,023) have been fully considered but are not found persuasive.

Applicant argues that the Examiner has provided no evidence or suggestion whatsoever in concluding that the wet granulation process of Botzolakis would provide intimate association between microcrystalline cellulose and silicon dioxide.

This is not persuasive because Botzolakis clearly teaches wet granulation and this is required for claims 1 and 2. By carrying out the wet granulation process where microcrystalline cellulose is used with the colloidal silicon dioxide and adsorbs on the drug particles (Col. 2, lines 11-17), the limitation of an intimate association between the microcrystalline cellulose and silicon dioxide is rendered obvious, since the "microcrystalline cellulose is **used with** the colloidal silicon dioxide".

Applicant argues that the Examiner's proposed modification to Botzolakis is unfounded and that "without the perspective of the instant invention, a person having ordinary skill in the art at the time of the invention simply would not make these modifications to Botzolakis."

Regarding claims 2 and 40, Applicant argues that the "Botzolakis process does not form a "pre-manufactured" excipient comprising agglomerated particles of microcrystalline cellulose in intimate association with the silicon dioxide, prior to the addition of a moisture-sensitive active agent, which advantageously protects the moisture-sensitive active, as provided by the subject invention." Applicant argues that there "are two separate and distinct types of wet granulation steps, and cannot simply be morphed as equivalent. They are not."

This is not persuasive because granulation of active ingredient as taught by Botzolakis leads to the microcrystalline cellulose and silicon dioxide in intimate or close association. Granulation of an active ingredient with microcrystalline cellulose and silicon dioxide by the wet granulation process of Botzolakis (where the steps comprise making a slurry of moisture sensitive active ingredient, colloidal silicon dioxide and microcrystalline cellulose, granulating and drying the slurry) appears equivalent to the granulation process where a slurry of microcrystalline cellulose and silicon dioxide is dried and then mixed with a moisture sensitive ingredient. This equivalence is based on the resulting granulate of a moisture sensitive ingredient which has microcrystalline cellulose and silicon dioxide adsorbed on the drug particles.

Applicant has not shown any unexpected results or a difference in the resulting granulate by varying the process steps. The order of the steps of preparing a slurry of microcrystalline cellulose and silicon dioxide is a manipulatable parameter that can be altered by a person having ordinary skill in the art, and based on the disclosure of

Botzolakis, the recited process steps of instant claims are obvious unless there is evidence of criticality or unexpected results.

Therefore, the rejection of 04/13/09 is maintained.

Claim Rejections - 35 USC § 103

12. Claims 4-5, 41-44 and 51-52 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Botzolakis et al. (US 4,910,023) in view of Schmidt et al. (US 4,605,666).

The teaching of Botzolakis is stated above.

Botzolakis does not expressly teach spray drying.

Schmidt teaches a "process for preparing a powder ... which is directly compressible into a tablet prepared by spray drying (a) an aqueous slurry of a water-soluble vitamin and a binder; (b) ... an adsorbent; and (c) a lubricant" (Abstract). It is taught that "the powders are directly compressible into tablets and will not demix" (Abstract). In example 1 an aqueous slurry of ascorbic acid, microcrystalline cellulose and water is spray dried and silicon dioxide is added (Col. 3, lines 29-49). The adsorbent is silicon dioxide (Col. 7, lines 14-15) and the binder is microcrystalline cellulose (Col. 8, lines 4-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of making a tablet comprising drying a slurry containing a moisture sensitive active ingredient, colloidal silicon dioxide and microcrystalline cellulose, as suggested by Botzolakis, vary the addition of a moisture

sensitive active ingredient to the slurry containing colloidal silicon dioxide and microcrystalline during the process of routine optimization, combine it with the process of spray drying to produce a compressible powder, and produce the instant invention.

One of ordinary skill in the art would do this because spray drying is a method for drying granulations that is known in the art, as evidenced by the teaching of Schmidt.

Regarding instant claim 4, the limitation of spray drying would have been obvious over the spray drying taught by Schmidt (Abstract).

Regarding instant claims 4, 41, 42 and 51, the limitation of the average particle size of about 30μm to about 250μm would have been obvious over the spray drying taught by Schmidt (Abstract) because by manipulating the spray drying process parameters, one with ordinary skill in the art would achieve the recited excipient particle size range unless there is evidence of criticality or unexpected results.

Regarding instant claims 5, 43, 44 and 52, the limitation of the bulk density of the excipient particles from about 0.2g/ml to about 0.6g/ml would have been obvious over the spray drying taught by Schmidt (Abstract) because by manipulating the spray drying process parameters, one with ordinary skill in the art would achieve the recited bulk density range unless there is evidence of criticality or unexpected results.

Response to Arguments

13. Applicant's arguments, see Page 12, filed 09/14/09, with respect to the rejection of claims 1-2, 7-12, 39-40 and 45-50 under 35 U.S.C. 103(a) as being unpatentable

over Botzolakis et al. (US 4,910,023) in view of Schmidt et al. (US 4,605,666) have been fully considered but are not found persuasive.

Applicant argues that "the Examiner has relied on a combination of Botzolakis and Schmidt in a further modified, unsupportable manner to create a new invention of her own design. It is respectfully submitted that the modifications that the Examiner suggests be done in order to combine these references in any meaningful way is simply a fabrication which is not supportable by any factual basis. The Examiner's proposed (combined) process would ignore required steps by Botzolakis making an agglomerate of drug/colloidal silicon dioxide; then adding a new step (varying the addition of another ingredient) not taught in either reference; then modifying a spray drying step described in Schmidt to produce the invention. The Examiner's recreation does not render the claims in question obvious, but rather is an example of an improper use of hindsight based solely on information provided in Applicants' claims."

This is not persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In this case, Botzolakis clearly teaches drying the granulation (Col. 3, line 46). One of ordinary skill in the art would find it obvious to use various methods of drying the

granulation, including spray drying (as taught by Schmidt), during the process of routine experimentation.

Therefore, the rejection of 04/13/09 is maintained.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 2, 4-5, 7-12, and 51-52 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 21, 23-27 of U.S. Patent No. 6,103,219. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1, 2, 4-5, 7-12, and 51-52 are drawn to a method for preparing a tablet comprising: forming an aqueous slurry containing a mixture of microcrystalline cellulose

in the form of a wet cake and silicon dioxide having a particle size from about 1 nm to about 100 μm; drying said slurry to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide, the amount of silicon dioxide being from about 0.1% to about 20% relative to the amount of microcrystalline cellulose, by weight; mixing an active ingredient with said excipient in a ratio from about 1:99 to about 99:1 to obtain a mixture; compressing said mixture into a tablet.

Claims 20, 21, 23-27 of U.S. Patent No. 6,103,219 ('219) are drawn to a method of preparing a solid dosage form comprising steps identical to those listed above from the instant application. One of ordinary skill in the art would recognize that the method of preparing a solid dosage form taught in '219, also includes tablets. The claimed subject matter of the instant application is taught by '219. Forming an aqueous slurry containing a mixture of microcrystalline cellulose in the form of a wet cake and silicon dioxide having a particle size from about 1 nm to about 100 μm; drying said slurry to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide, the amount of silicon dioxide being from about 0.1% to about 20% relative to the amount of microcrystalline cellulose, by weight; mixing an active ingredient with said excipient in a ratio from about 1:99 to about 99:1 to obtain a mixture; and incorporating said mixture into a plurality of solid unit doses.

Claim 2 of the instant application is anticipated by claim 21 of '219.

Claim 4 of the instant application is anticipated by claim 24 of '219.

Claim 5 of the instant application is anticipated by claim 25 of '219.

Claim 7 of the instant application is anticipated by claim 27 of '219.

Claims 8-12 of the instant application are drawn to a method of further drying the aqueous slurry so the moisture content of the excipient particles can be controlled. Since the technique of spray drying is used and it is well known in the art, varying the parameters of the spray drying procedure could modify the moisture content of the excipient particles.

Claim 51 of the instant application is anticipated by claim 23 of '219.

Claim 52 of the instant application is anticipated by claim 26 of '219.

Therefore, the claimed subject matter, i.e. a method for preparing a tablet by mixing an active ingredient with the excipient (prepared after forming a slurry containing a mixture microcrystalline cellulose and silicon dioxide, and drying the slurry to get agglomerated particles of microcrystalline cellulose in intimate association with silicon dioxide) and compressing the mixture into a tablet, are anticipated by '219.

16. Claims 39-42, and 46-50 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 20, 24, 30, 32, and 33 of U.S. Patent No. 6,746,693 in view of claims 25-27 of U.S. Patent No. 6,103,219. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims are drawn to a method for preparing a tablet, comprising the steps of: (a) forming an aqueous slurry of microcrystalline cellulose in the form of wet cake; (b) forming an aqueous slurry of silicon dioxide having a particle size of from about 1 to

about 100μm; (c) separately introducing said microcrystalline slurry and said silicon dioxide slurry separately into a drying apparatus for combination therein, to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said silicon dioxide, the amount of silicon dioxide being from about 0. 1% to about 20% relative to the amount of microcrystalline cellulose, by weight; (d) mixing an active ingredient with said excipient in a ratio of from about 1:99 to about 99:1 to obtain a mixture; (e) compressing said mixture into a tablet.

Claims 19, 20, 24, 30, 32, and 33 of U.S. Patent No. 6,746,693 ('693) are drawn to a method of preparing a solid dosage form comprising steps identical to those listed above from the instant application. One of ordinary skill in the art would recognize that the method of preparing a solid dosage form taught in '693, also includes tablets. The claimed subject matter of the instant application is taught by '693. Forming separate aqueous slurries of microcrystalline cellulose and silicon dioxide and introducing these slurries separately into a drying apparatus to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with the silicon dioxide, the amount of silicon dioxide being from about 0.1% to about 20% relative to the amount of microcrystalline cellulose, mixing an active ingredient with the agglomerated particles, and incorporating the mixture into a plurality of solid unit doses.

Claim 39 of the instant application includes a ratio of active ingredient and excipient of 1:99 to about 99:1. Claim 19 of '693 does not teach this ratio. However, in US 6,103,219 ('219), claim 20 teaches mixing an active ingredient with an excipient in a ratio from about 1:99 to about 99:1. It would have been obvious to one having ordinary

skill in the art at the time the invention was made to combine the teaching of '693 (which includes using separate slurries of microcrystalline cellulose and silicon dioxide) with the ratio of active ingredient to excipient taught by '219.

Claim 40 of the instant application is anticipated by claims 20 (further comprises wet granulating the mixture before incorporating into solid unit doses) and 24 (colloidal silicon dioxide) of '693.

Claim 41 of the instant application is anticipated by claim 30 (particle size from 10μm to 1000μm) and claim 37 (spray drying) of '693.

Claim 42 of the instant application is anticipated by claim 32 of '693.

Claims 46-50 of the instant application are anticipated by claim 33 of '693 (which teaches that the moisture content of the particles is from 0.5-15%). Claims 47, 48, 49, and 50 are covered by the range 0.5-15% of the moisture content.

Therefore, the claimed subject matter, i.e. a method for preparing a tablet by mixing an active ingredient with the excipient (prepared after forming separate slurries of microcrystalline cellulose and silicon dioxide and drying the slurry to get agglomerated particles of microcrystalline cellulose in intimate association with silicon dioxide) and compressing the mixture into a tablet, are anticipated by '693.

Response to Arguments

17. Applicant's arguments, see Page 7, filed 09/14/09, with respect to the obviousness type double patenting rejections have been fully considered. Applicant argues that the Examiner has not indicated a deficiency in the Terminal Disclaimers. The Terminal Disclaimers filed on 01/12/09 were disapproved. The reason given was

that the attorney was not listed on the Power of Attorney. Until such time that the Terminal Disclaimers are approved, the double patenting rejections will be maintained.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615